

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a redetermination;

(ii) Describe both the standard and expedited redetermination processes, including the enrollee's right to request, and conditions for obtaining, an expedited redetermination, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by CMS.

(d) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the timeframe specified in paragraph (a) of this section, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

§ 423.576 Effect of a coverage determination.

The coverage determination is binding on the Part D plan sponsor and the enrollee unless it is reviewed and revised under § 423.580 through § 423.630 or is reopened and revised under § 423.634.

§ 423.578 Exceptions process.

(a) *Requests for exceptions to a plan's tiered cost-sharing structure.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's statement under paragraph (a)(4) of this section.

(1) The exceptions procedures must address situations where a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.

(2) The exceptions criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a determination made by the enrollee's prescribing physician under paragraph (a)(4) of this section.

(ii) Consideration of whether the requested Part D drug that is the subject of the exceptions request is the therapeutic equivalent, as defined in § 423.100, of any other drug on the plan's formulary.

(iii) Consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested prescription drug that is the subject of the exceptions request.

(3) An enrollee or the enrollee's prescribing physician may file a request for an exception.

(4) A prescribing physician must provide an oral or written supporting statement that the preferred drug for the treatment of the enrollee's condition—

(i) Would not be as effective for the enrollee as the requested drug;

(ii) Would have adverse effects for the enrollee; or

(iii) Both paragraphs (a)(4)(i) and (a)(4)(ii) of this section apply.

(5) If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement to demonstrate the medical necessity of the drug. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

(6) In no case is a Part D plan sponsor required to cover a non-preferred drug at the generic drug cost-sharing level if the plan maintains a separate tier dedicated to generic drugs.

(7) If a Part D plan sponsor maintains a formulary tier in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception.

(b) *Request for exceptions involving a non-formulary Part D drug.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and

maintain exceptions procedures subject to CMS' approval for receipt of an off-formulary drug. The Part D plan sponsor must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician's statement under paragraph (b)(5) of this section, and that the drug would be covered but for the fact that it is an off-formulary drug. Formulary use includes the application of cost utilization tools, such as a dose restriction, including the dosage form, that causes a particular Part D drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular Part D drug not to be covered until the requirements of the plan's coverage policy are met, or a therapeutic substitution requirement.

(1) The plan's formulary exceptions process must address each of the following circumstances:

(i) Situations where a formulary changes during the year, and situations where an enrollee is already using a given drug.

(ii) Continued coverage of a particular Part D prescription drug that the Part D plan sponsor is discontinuing coverage on the formulary for reasons other than safety or because the Part D prescription drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer.

(iii) An exception to a plan's coverage policy that causes a Part D prescription drug not to be covered because of cost utilization tools, such as a requirement for step therapy, dosage limitations, or therapeutic substitution.

(2) The exception criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a prescribing physician's determination made under paragraph (b)(5) of this section;

(ii) A process for gathering and comparing applicable medical and scientific evidence on the safety and effectiveness of the requested non-formulary drug with the formulary drug for the enrollee, including safety infor-

mation generated by an authoritative government body; and

(iii) A description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug.

(3) If the Part D plan sponsor covers a non-formulary drug, the cost(s) incurred by the enrollee for that drug are treated as being included for purposes of calculating and meeting the annual out-of-pocket threshold.

(4) An enrollee, the enrollee's appointed representative, or the prescribing physician (on behalf of the enrollee) may file a request for an exception.

(5) A prescribing physician must provide an oral or written supporting statement that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition because—

(i) All of the covered Part D drugs on any tier of a plan's formulary for treatment for the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects for the enrollee, or both;

(ii) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements—

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(B) Has caused or based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee; or

(iii) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and

known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

(6) If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

(c) *Requirements for exceptions*—(1) *General rule.* A decision by a Part D plan sponsor concerning an exceptions request under this section constitutes a coverage determination as specified at § 423.566.

(2) When a Part D plan sponsor does not make a timely decision. If the Part D plan sponsor fails to make a decision on an exceptions request and provide notice of the decision within the timeframe required under § 423.568(a) or § 423.572(a), as applicable, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(3) *When a tiering exceptions request is approved.* Whenever an exceptions request made under § 423.578(a) is approved, the Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies for preferred drugs, and may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(i) The enrollee's prescribing physician continues to prescribe the drug;

(ii) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(iii) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(4) *When a non-formulary exceptions request is approved.* Whenever an exceptions request made under § 423.578(b) is approved—

(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician continues to prescribe the drug;

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(ii) The Part D plan sponsor must not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

(iii) An enrollee may not request a tiering exception for a non-formulary prescription drug approved under § 423.578(b).

(d) *Notice regarding formulary changes.* Whenever a Part D plan sponsor removes a covered part D drug from its formulary or makes any changes in the preferred or tiered cost-sharing status of such a drug, the Part D plan sponsor must provide notice in accordance with § 423.120(b)(5).

(e) *Limitation of the exceptions procedures to Part D drugs.* Nothing in this section may be construed to allow an enrollee to use the exceptions processes set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug.

(f) *Implication of the physician's supporting statement.* Nothing in this section should be construed to mean that the physician's supporting statement required for an exceptions request will result in an automatic favorable determination.

§ 423.580 Right to a redetermination.

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.634) may request that it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. An enrollee or an enrollee's prescribing